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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/667,170 | 09/20/2000 | Steven G. Reed | 210121.475C7 | 8291 |

7590 05/27/2003

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/667,170 | REED ET AL. |
| | Examiner | Art Unit |
| | James Martinell | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,9-15 and 17-39 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4-8 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9,11&12</u> . | 6) <input type="checkbox"/> Other: _____ . |

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Claims 1-3, 9-15, and 17-39 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14. In addition, applicants have elected SEQ ID NO: 440 for examination. It is noted the SEQ ID NO: 440 is not a species, but is a separate and distinct from the other SEQ ID NOs mentioned in the claims. Thus, election of species practice does not apply to the instant application.

The disclosure is objected to because of the following informalities.

- (a) Claim 8 should not recite claims 4 and 5 because claims 4 and 5 already include the complements.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "variant thereof" (claims 4 and 5) is vague and indefinite because it is not clear how much a sequence may vary and still be embraced by the claims. Thus, the metes and bounds of the claims are not clear.
- (b) The recitation of "such that the ability of the variant to react with antigen-specific antisera is not substantially diminished" (claim 4) is vague, indefinite, and incomplete. There is no frame of reference for the reactivity mentioned in

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the claims. In addition, the application does not distinguish between substantial diminution of reactivity and insubstantial diminution of reactivity.

- (c) The recitation of "antigen-specific antisera" (claim 4) has no antecedent basis. Hence, the claim is incomplete.
- (d) Each of claims 4-8 and 16 is vague and indefinite because it claims more than was elected for examination.
- (e) Claim 16 is incomplete because it depends from non-elected claims.

Claims 4-8 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides that encode polypeptides for which the open reading frame is disclosed in the polynucleotide encoding that polypeptide (*e.g.*, see recitations in claims 1 (claim 16 depends from claim 1 *via* claim 12) and 4-7), does not reasonably provide enablement for all polynucleotides that encode polypeptides for which the open reading frame is not disclosed in the polynucleotide encoding that polypeptide (*e.g.*, see recitations in claims 1 (claim 16 depends from claim 1 *via* claim 12) and 4-7). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application does not disclose all possible open reading frames for the elected polynucleotide (SEQ ID NO: 440)). Thus, one of skill in the art cannot use polynucleotides that encode polypeptides not disclosed as being encoded in SEQ ID NO: 440.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 4, 7, and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hillier et al (GenBank® Accession No. W00842 (4/18/96)). Hillier et al was published as a CD-ROM in August 1996. Hillier et al discloses a DNA that shares 321 contiguous nucleotides with SEQ ID NO: 440 with 3 mismatches (see the alignment attached to the copy of the reference). Thus, the claims embrace the DNA of Hillier et al.

Claims 4, 7, and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by either one of Cheng et al (Genome Res. 9 (10), 989 (1999)) or Williams et al (WO 9938972-A2). Cheung et al discloses a DNA that shares 128 contiguous nucleotides with SEQ ID NO: 440 (see the alignment attached to the copy of the reference). Williams et al discloses a DNA that shares 414 contiguous nucleotides with SEQ ID NO: 440 (see the alignment attached to the title page of the reference (Applicants cited Williams et al on form PTO-1449, but the copy of the reference supplied lacked the Sequence Listing. This Office action contains a copy of SEQ ID NO: 3998 of Williams et al which contains the sequence that matches SEQ ID NO: 440 over 414 nucleotides)). Thus, the claims embrace the DNAs of Cheung et al and Williams et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
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